

REMARKS/ARGUMENTS

The Office Action mailed October 14, 2008 has been received and carefully noted. Claims 61-68 and 79-83 were examined and rejected. Claims 1-60 and 69-78 have been previously cancelled.

Applicants amend claims 61, 62, and 65-66 and submit additional claim 84 for consideration. Applicants submit that no new matter is added herein. Amendments to claims 61, 62, and 65-66 and additional claim 84 are supported at least at FIGs. 82-85 and corresponding paragraphs 453, 456, and 458-462 of the application.

Applicants respectfully request reconsideration of claims 61-68 and claims 79-83; and consideration of claim 84 in view of the following remarks.

I. Claim Rejections – 35 U.S.C. § 102

Claims 61-66, 68 and 79-83 are rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 6,015,402 to Sahota (“Sahota”). It is axiomatic that to be anticipated, every limitation of the claim must be disclosed in a single reference.

Applicants respectfully disagree with the rejection above for at least the reason that the cited reference does not disclose a method including inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest during the occlusion of the blood vessel; and perfusing a blood and a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61.

Sahota uses multiple balloons to isolate multiple sections of a vessel for treatment by injection of drugs through ports 56 to those isolated sections (prior to injection blood can be suctioned out of the isolated region) (column 7, lines 13-43). Sahota also uses ports 34 and 36 located distal and proximal to the balloons to allow blood flow to bypass the isolate regions (column 7, lines 4-9; and Figs. 8-9). So, ports 56 provide drugs to regions that are separated from, and not in fluid communication with, the distal and proximal end of the multiple balloons, which is where ports 34 and 36 located (Figs. 8-9). Thus, the teachings of Sahota teach against and can not provide perfusing a treatment agent through the passageway.

Therefore, Sahota does not teach or enable perfusing a blood and a treatment agent, as

required by claim 61.

On the other hand, for example, without limitation thereto, by perfusing blood and treatment agent during the occlusion of the blood vessel, embodiments described in the specification, for example, without limitation thereto provide the unexpected benefits of: (1) allowing drugs to be injected distal to the balloon, and then allowing the blood and drugs to be perfused using the ports located distal and proximal to the balloon to allow blood flow and avoid ischemia (see at least para. 458 of the application); (2) so that the drugs can be injected, and the blood and drugs can be perfused repeatedly, while the balloon stays inflated (e.g., does not need to be deflated and reinflated) to occlude the blood vessel (see at least FIG. 82-85; paras. 447 and 461 of the application; and claims 63 and 65); (3) allowing the amount of blood and treatment agent perfused to be controlled over a desirable range, such as by retracting and extending a guide wire in a lumen (see at least FIG. 88; paras. 459-462 of the application; and claims 64 and 66). However, Sahota does not contemplate or enable such benefits.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 63 for at least the reason that Sahota does not disclose a method wherein inflating includes inflating the balloon for a first period of time to occlude the blood vessel for the first period of time and perfusing includes deflating the balloon for a second period of time; and at least one more repetition of inflating, infusing, and deflating as required by claim 63. As noted above for claim 61, Sahota only teaches suctioning blood from isolate regions, or using proximal and distal ports 34 and 36 to perfuse blood around isolated drug treated regions. Thus, the Patent Office has not identified and Applicants are unable to identify any disclosure in Sahota of the above noted limitations of claim 63. Hence, Applicants respectfully request the Patent Office withdraw the rejection of claim 63 for this additional reason.

Moreover, in addition to the dependence upon allowable base claim 61, Applicants respectfully disagree with the rejection of claim 64 for at least the reason that Sahota does not disclose or enable retracting a guidewire from a location distal to at least one hole to a location proximal to the at least one hole to cause profusion through the at least one hole as required by claim 64. However, the Patent Office has not identified and Applicants are unable to find any disclosure or enablement of a guidewire of Sahota being retracted to cause profusion through at least one hole in the exterior surface of a canula as required by claim 64. As noted above for claim 61, Sahota only teaches suctioning blood from isolate regions, or using proximal and distal

ports 34 and 36 to perfuse blood around isolated drug treated regions. Hence, for at least this additional reason, Applicants respectfully request the Patent Office withdraw the rejection of claim 64.

Furthermore, in addition to its dependence upon allowable base claim 61, Applicants respectfully disagree with the rejection of claim 66 for at least the reason that Sahota does not disclose or enable retracting a distal end of a guidewire to control an amount of a blood and treatment agent profusion, as required by claim 66. As noted above for claim 61, Sahota only teaches suctioning blood from isolate regions, or using proximal and distal ports 34 and 36 to perfuse blood around isolated drug treated regions. Hence, for at least this additional reason, Applicants respectfully request that the Patent Office withdraw the rejection of claim 66.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 82 for at least the reason that Sahota does not disclose or enable retracting a distal end of a guidewire to a location proximal to at least one hole to allow profusion, as required by claim 83. An argument analogous to the one above for claim 64 applies here as well. Hence, for at least this additional reason, Applicants respectfully request withdrawal of the rejection above of claim 83.

II. Claim Rejections – 35 U.S.C. § 103

Claims 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota in view of U.S. Patent No. 6,805,860 to Alt (Alt). For a claim to be obvious, each limitation of the claim must be taught or suggested by at least one properly combined reference. Furthermore, the combination of elements must be “more than a predictable use of prior art elements according to their established functions.” (see KSR International Company v. Teleflex Inc., No. 04-1350 (Supreme Court, April 30, 2007)).

Applicants respectfully disagree with the rejection above for at least the reason that Alt does not cure the deficiencies of Sahota noted above for claim 61, from which the above noted claim depends.

Alt teaches using autologous adult stem cells which are derived from the same patient to replace necrotic tissue of a failing organ of that patient, such as a heart after an MI (see col. 5, line 52 through col. 6, line 32). However, the Patent Office has not identified and Applicants are unable to find any teaching in Alt of the above-noted limitations of claim 61.

III. Dependent Claims

Any dependent claims not mentioned above are submitted as being patentable for at least the reasons provided in support of their base claim, as well as additional limitations of each dependent claim.

Hence, Applicants respectfully request the Patent Office withdraw all the rejections above.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP

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Angelo J. Gaz

Registration No. 45,907

1279 Oakmead Parkway
Sunnyvale, California 94085-4040
Telephone (310) 207-3800
Facsimile (408) 720-8383

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted to the United States Patent and Trademark Office electronically via EFS Web on the date shown below.


Jessica Hudster

12/19/08
Date